11-1-2021

PURPOSE

The purpose of this policy is to establish for the Michigan Department of Health and Human Services (MDHHS) a retention schedule for newborn screening dried blood spot specimens.

DEFINITIONS

NBS: Newborn screening is a comprehensive program that tests for and provides long and short term follow up and medical management for children with disorders identified through the program. (PA 368 of 1978, 333.5431, 333.5430).

DBS: Dried blood spot is the blood specimen collected from the heel of a newborn post- birth on a filter paper collection device. After drying, the blood and patient identifying information contained on the same paper collection device are sent to the MDHHS Bureau of Laboratories for testing.

POLICY

MDHHS will maintain, or cause to be stored, newborn screening dried blood spots up to 100 years from specimen receipt date. A parent or legal guardian may request that their child's DBS not be used for any research by contacting MDHHS until their child reaches 18 years of age. Upon reaching 18 years of age, the individual must make the request. A parent or legal guardian may request that their child's specimen be destroyed by providing the name, date of birth and their relationship to the individual from whom the specimen was collected and must provide copies of the individual's birth certificate and a government-issued identification (for example, driver's license or passport) to confirm that they have authority to make such a request. Upon reaching 18 years of age, the individual must make the request and provide copies of their birth certificate and a government-issued identification.

MDHHS retains qualified ownership of DBS while in storage. The department may release part, or all, of the residual DBS upon written request of the individual for research studies or other uses. MDHHS may release part, or all, of the de-identified specimen for NBS quality assurance and test development or public health or medical research with appropriate approval of the departments scientific advisory panel and Institutional Review Board. MDHHS will reserve part of the specimen solely for the use of the individual or parent/guardian, unless requested otherwise by an authorized individual.

LABORATORIES STATE OF MICHIGAN

11-1-2021

Retention schedules for DBS collected for other tests (such as HIV serology, lead) will be determined by Bureau of Laboratory policy.

PROCEDURE

The Bureau of Laboratories Newborn Screening section manager:

- Processes and packages dried blood spots for storage and maintains specimen identification.
- Oversees and confirms in writing the destruction of specimens when request for destruction has been received and confirmed as authentic from the individual or parent or legal guardian of the individual.

The Bureau of Laboratory Administrator identifies resources for an adequate and secure storage environment of the dried blood spot specimens and assures this environment protects the integrity of the biological components of the specimen.

REFERENCES

<u>Association of Public Laboratories(APHL)/Programs/Newborn Screening & Genetics.</u>

Therrell, B.L, H.W. Hannon, et al. 1996. Guidelines for the retention, storage and use of residual dried blood spot samples after newborn screening analysis: Statement of the Council of Regional Networks for Genetic Services. Biochemical and Molecular Med. 57:116-124. in US National Library Of Medicine National Institutes of Health.

MDHHS/Adult & Children's Services/Children & Families/Hereditary
Disorders/ Michigan Newborn Screening Program/ State of
Michigan Links: Michigan Bio Trust for Health:

MDHHS-5683, Residual Newborn Screening Blood Spot Directive. http://michigan.gov/documents/mdhhs/MDHHS-5683 610453 7.dot

Michigan Public Health Code, Act 368 of 1978, 333.5431, 333.5430

CONTACT

For additional information concerning this policy, contact the Newborn Screening Laboratory by phone at 517-241-6366 or email at SeeterlinM@Michigan.gov.

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